IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

NATHANIEL SMITH,	:	CIVIL ACTION
Plaintiff,	:	NO. 02-CV-4503
vs.	:	
BAYER CORPORATION, BAYER AG, GLAXOSMITHKLINE, PLC, GLAXOSMITHKLINE, SMITHKLINE BEECHAM	:	(Pending transfer to *In re Baycol Products Litigation* MDL 1431 (D. Minn.))
Defendants.	:	

ANSWER AND DEFENSES OF DEFENDANT BAYER AG

Defendant BAYER AG answers the Complaint in this action as follows:

1. The allegations in paragraph 1 of the Complaint set forth legal conclusions to which no response is required. To the extent that a response is required, Bayer AG is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 1, except that Bayer AG denies that Plaintiff is entitled to any relief.

2. Bayer AG is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2.

3. Bayer AG admits that Bayer Corporation is a corporation and that Bayer Corporation's principal place of business is located at 100 Bayer Road, Pittsburgh, PA. Bayer AG denies the remaining allegations in paragraph 3.

4. Bayer AG admits that it is a German corporation with its principal place of business in Leverkusen, Germany. Bayer AG denies the remaining allegations in paragraph 4.

Bayer AG further states that it does not contest specific personal jurisdiction over Bayer AG in this action, but Bayer AG denies that general jurisdiction exists over Bayer AG in this action.

5. Bayer AG denies the allegations in paragraph 5. For a further response, Bayer AG states that to the extent that the Complaint contains allegations that are directed to Bayer Corporation by use of the term "defendants" or otherwise, no answer is required by Bayer AG, and Bayer AG therefore makes no response in this Answer to the allegations that are directed to Bayer Corporation.

6. Bayer AG admits that Bayer Corporation is a wholly owned subsidiary of Bayer AG. Bayer AG denies any remaining allegations in paragraph 6.

7. Because of the vagueness and ambiguity in the allegations in paragraph 7, Bayer AG is without knowledge or information sufficient to form a belief as to the truth of such allegations.

8. Bayer AG admits, on information and belief, that GlaxoSmithKline plc is an English public limited company with its principal place of business in England. Bayer AG is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 8.

9. Bayer AG is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 9.

10. Bayer AG admits, on information and belief, that SmithKline Beecham Corporation is a Pennsylvania corporation with its principal place of business in Pennsylvania. Bayer AG is without knowledge and information sufficient to form a belief as to the truth of the remaining allegations in paragraph 10.

11. Bayer AG is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 11.

12. Bayer AG admits that cerivastatin sodium, a prescription medication, was sold under the trade name Baycol® in the United States and the trade name Lipobay® in certain countries outside of the United States. Bayer AG denies the remaining allegations in paragraph 12.

13. Bayer AG admits that cerivastatin sodium, which was sold in the United States under the trade name Baycol®, was manufactured in Germany. Bayer AG denies any remaining allegations in paragraph 13.

14. Bayer AG admits that prior to August 8, 2001, Bayer AG manufactured cerivastatin sodium in Germany and Bayer Corporation sold cerivastatin sodium under the trade name Baycol® in the United States. Because of the vagueness and ambiguity of the remaining allegations in paragraph 14, Bayer AG is without knowledge or information sufficient to form a belief as to the truth of such allegations.

15. Bayer AG denies that Baycol® is a registered trademark of GW USA, Inc. Bayer AG is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 15.

16. Because of the vagueness and ambiguity of the allegations in paragraph 16, Bayer AG is without knowledge or information sufficient to form a belief as to the truth of such allegations.

17. Bayer AG admits that Plaintiff purports to commence an action seeking relief, but Bayer AG denies that Plaintiff is entitled to any relief. Bayer AG admits that Baycol® is a prescription medication also known as cerivastatin sodium, and that cerivastatin sodium is

known as Lipobay® in certain countries outside of the United States. Bayer AG denies that Plaintiff was injured as a result of ingestion of Baycol® as sold by Bayer Corporation. Bayer AG is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 17.

18. Bayer AG denies that it promoted and/or sold Baycol® in the United States. Bayer AG admits that, prior to August 8, 2001, Bayer Corporation promoted and sold Baycol® in the United States, that prior to August 8, 2001, SmithKline Beecham Corporation d/b/a GlaxoSmithKline participated in the promotion of Baycol® in the United States, and that it is estimated that, prior to August 8, 2001, more than 700,000 persons took Baycol® in the United States. Because of the vagueness and ambiguity of the remaining allegations in paragraph 18, Bayer AG is without knowledge or information sufficient to form a belief as to the truth of such allegations.

19. Bayer AG denies the allegations in paragraph 19.

20. Bayer AG denies the allegations in paragraph 20.

21. Bayer AG denies the allegations in paragraph 21.

22. Bayer AG denies the allegations in paragraph 22.

23. Bayer AG admits that, prior to August 8, 2001, Bayer Corporation marketed Baycol® in the United States as safe for use in accordance with prescribing information and under the care of a physician or other health care provider. Bayer AG denies the remaining allegations in paragraph 23.

24. Bayer AG denies the allegations in paragraph 24.

25. Bayer AG denies the allegations in paragraph 25.

26. Bayer AG denies the allegations in paragraph 26.

27. Bayer AG denies the allegations in paragraph 27 to the extent that they relate to Bayer AG. Bayer AG admits that, prior to August 8, 2001, Bayer Corporation promoted, marketed, distributed and sold Baycol®, a prescription medication, in the United States, including in Pennsylvania, and that prior to August 8, 2001, SmithKline Beecham Corporation d/b/a GlaxoSmithKline participated in the promotion of Baycol® in the United States. Bayer AG admits that Bayer Corporation has promoted, marketed, distributed and/or sold certain prescription and non-prescription drug products in Pennsylvania. Bayer AG denies that Bayer Corporation and SmithKline Beecham d/b/a GlaxoSmithKline manufactured Baycol®. Because of the vagueness and ambiguity of the remaining allegations in paragraph 27, Bayer AG is without knowledge or information sufficient to form a belief as to the truth of such allegations.

28. Bayer AG is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 28.

29. Bayer AG denies the allegations in paragraph 29.

30. Bayer AG admits that at least five other statins have been approved by the United States Food and Drug Administration (the "FDA") for sale in the United States, and that statins block the activity of an enzyme that is involved in the production of cholesterol in the liver. Bayer AG is without knowledge or information sufficient to form a belief regarding the truth of the remaining allegations in paragraph 30.

31. Bayer AG denies the allegations of paragraph 31.

32. Bayer AG denies the allegations of paragraph 32.

33. Bayer AG denies the allegations of paragraph 33.

34. Bayer AG admits that in June 1997, the FDA approved Bayer Corporation's application to market Baycol® in the United States, that prior to August 8, 2001,

Bayer Corporation marketed Baycol® in the United States, and that prior to August 8, 2001, SmithKline Beecham Corporation d/b/a GlaxoSmithKline participated in the promotion of Baycol® in the United States. Bayer AG admits that Bayer Corporation voluntarily withdrew Baycol® from the market in the United States on August 8, 2001. Bayer AG denies the remaining allegations in paragraph 34.

35. Bayer AG admits that the FDA made an announcement regarding the voluntary withdrawal of Baycol® from the market in the United States. That announcement is in writing and speaks for itself. To the extent that Plaintiff's allegations regarding the content of that announcement are inconsistent with the actual language of the announcement, Bayer AG denies those allegations. Because of the vagueness and ambiguity of the remaining allegations in paragraph 35, Bayer AG is without knowledge or information sufficient to form a belief as to the truth of such allegations.

36. Because of the vagueness and ambiguity of the allegations in paragraph 36, Bayer AG is without knowledge or information sufficient to form a belief as to the truth of such allegations.

37. Bayer AG denies the allegations in paragraph 37.

38. Bayer AG admits that Bayer Corporation discontinued sampling of the 0.8 mg dose of Baycol® through Bayer Corporation's sales representatives in 2001. Bayer AG denies the remaining allegations in paragraph 38.

39. Paragraph 39 apparently purports to describe the FDA’s announcement regarding Bayer Corporation's voluntary withdrawal of Baycol® from the market in the United States on August 8, 2001, which announcement is in writing and speaks for itself. To the extent that Plaintiff's allegations regarding the content of that announcement are inconsistent with the

actual language of the announcement, Bayer AG denies those allegations. Because of the vagueness and ambiguity of the remaining allegations in paragraph 39, Bayer AG is without knowledge or information sufficient to form a belief as to the truth of such allegations.

40. Bayer AG admits that Baycol® is one of several drug products generally included within the class of drug products known as statins, which block the activity of an enzyme that is involved in the production of cholesterol in the liver. Bayer AG also admits that all statins have been associated with reports of rhabdomyolysis. Bayer AG also admits that rhabdomyolysis is a condition that results from the breakdown of muscle cells and the release of contents of muscle cells into the bloodstream, that the symptoms of rhabdomyolysis may include muscle pain and tenderness, and that in severe cases involving persons susceptible to renal injury, rhabdomyolysis may involve renal failure, which can be fatal. Because of the vagueness and ambiguity in the remaining allegations in paragraph 40, Bayer AG is without knowledge or information sufficient to form a belief as to the truth of those allegations.

41. Bayer AG denies the allegations in paragraph 41.

42. Paragraph 42 apparently purports to describe the FDA's announcement regarding Bayer Corporation's voluntary withdrawal of Baycol® from the market in the United States on August 8, 2001. The FDA's announcement is in writing and speaks for itself. To the extent that Plaintiff's allegations regarding the content of that announcement are inconsistent with the actual language of the announcement, Bayer AG denies those allegations. Bayer AG admits that the symptoms of rhabdomyolysis may include muscle pain, tenderness and weakness, malaise, fever, dark urine, nausea and vomiting, that the muscle pain may be diffuse or specific to particular muscle groups, and that in severe cases involving persons susceptible to renal

injury, rhabdomyolysis may involve renal failure, which can be fatal. Bayer AG denies the remaining allegations in paragraph 42.

43. Because of the vagueness and ambiguity of the allegations in paragraph 43, Bayer AG is without knowledge or information sufficient to form a belief as to the truth of such allegations.

44. Bayer AG denies the allegations in paragraph 44.

45. Bayer AG denies the allegations in paragraph 45.

46. Bayer AG denies the allegations in paragraph 46.

47. Bayer AG denies the allegations in paragraph 47.

48. Bayer AG denies the allegations in paragraph 48.

49. Bayer AG denies the allegations in paragraph 49.

50. Bayer AG denies the allegations in paragraph 50.

51. Bayer AG denies the allegations in paragraph 51.

52. Bayer AG denies the allegations in paragraph 52, except that Bayer AG admits that Baycol® as sold by Bayer Corporation was safe.

53. Bayer AG denies the allegations in paragraph 53.

54. The February 18, 1998 announcement referred to in paragraph 54 is in writing and speaks for itself. To the extent that Plaintiff's allegations regarding the content of that announcement are inconsistent with the actual language of the announcement, Bayer AG denies those allegations. Because of the vagueness and ambiguity of the remaining allegations in paragraph 54, Bayer AG is without knowledge or information sufficient to form a belief as to the truth of such allegations.

55. Bayer AG admits that the FDA approved Bayer Corporation's application to market a 0.4 mg dose of Baycol® in the United States in May 1999. Bayer AG denies the remaining allegations in paragraph 55.

56. Because of the vagueness and ambiguity of the allegations in paragraph 56, Bayer AG is without knowledge or information sufficient to form a belief as to the truth of such allegations.

57. Bayer AG admits that paragraph 57 purports to describe an October 25, 1999 letter from Michael A. Misocky of the FDA's Division of Drug Marketing, Advertising and Communications to Bayer Corporation and certain written materials referred to in that letter. Those documents, being in writing, speak for themselves. To the extent that Plaintiff's allegations regarding the contents of those documents are inconsistent with the actual language of the documents, Bayer AG denies those allegations. Bayer AG denies the remaining allegations in paragraph 57.

58. Because of the vagueness and ambiguity of the allegations in paragraph 58, Bayer AG is without knowledge or information sufficient to form a belief as to the truth of such allegations.

59. Bayer AG admits that the FDA approved Bayer Corporation's application to market a 0.8 mg dose of Baycol® in the United States in July 2000. Bayer AG denies the remaining allegations in paragraph 59.

60. Bayer AG admits that Bayer Corporation issued a "Dear Health Care Professional" letter in May 2001. That letter, being in writing, speaks for itself. To the extent that Plaintiff's allegations regarding the content of that letter are inconsistent with the actual

language of the letter, Bayer AG denies those allegations. Bayer AG denies the remaining allegations in paragraph 60.

61. Bayer AG admits that paragraph 61 purports to quote portions of a letter dated August 8, 2001 from E. Paul MacCarthy, M.D., Vice President of Bayer Corporation, addressed to healthcare professionals. That letter, being in writing, speaks for itself. To the extent that Plaintiff's allegations regarding the content of that letter are inconsistent with the actual language of the letter, Bayer AG denies those allegations. Bayer AG denies the remaining allegations in paragraph 61.

62. Bayer AG admits that, on August 8, 2001, Bayer Corporation voluntarily withdrew Baycol® from the market in the United States. Bayer AG denies the remaining allegations in paragraph 62.

63. Paragraph 63 refers to a document which is in writing and speaks for itself. To the extent that Plaintiff's allegations regarding that document are inconsistent with the actual language of the document, Bayer AG denies those allegations. Bayer AG denies the remaining allegations in paragraph 63.

64. Bayer AG denies the allegations in paragraph 64.

65. Bayer AG denies the allegations in paragraph 65.

66. Bayer AG denies the allegations in paragraph 66.

67. Bayer AG admits that, prior to August 8, 2001, SmithKline Beecham Corporation d/b/a GlaxoSmithKline participated in the promotion of Baycol® in the United States. Because of the vagueness and ambiguity of the remaining allegations in paragraph 67, Bayer AG is without knowledge or information sufficient to form a belief as to the truth of such allegations.

68. Bayer AG admits that, prior to August 8, 2001, Bayer Corporation promoted, marketed and distributed Baycol® in the United States. Because of the vagueness and ambiguity of the remaining allegations in paragraph 68, Bayer AG is without knowledge or information sufficient to form a belief as to the truth of such allegations.

69. Bayer AG is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 69.

70. Bayer AG is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 70.

71. In response to the allegations in paragraph 71, Bayer AG incorporates by reference its responses to paragraphs 1 through 70 of the Complaint.

72. Bayer AG denies the allegations in paragraph 72.

73. Paragraph 73 sets forth conclusions of law to which no response is required. To the extent that a response is required, Bayer AG denies the allegations in paragraph 73.

74. Paragraph 74 sets forth conclusions of law to which no response is required. To the extent that a response is required, Bayer AG denies the allegations of paragraph 74.

75. Paragraph 75 sets forth conclusions of law to which no response is required. To the extent that a response is required, Bayer AG denies the allegations in paragraph 75.

COUNT I

76. In response to the allegations in paragraph 76, Bayer AG incorporates by reference its responses to paragraphs 1 through 75 of the Complaint.

77. Bayer AG denies the allegations in paragraph 77.

78. Bayer AG denies the allegations in paragraph 78.

79. Bayer AG denies the allegations in paragraph 79.

80. Bayer AG denies the allegations in paragraph 80, including subparts (a) through (i).

81. Bayer AG denies the allegations in paragraph 81.

COUNT II

82. In response to the allegations in the first sentence of paragraph 82, Bayer AG incorporates by reference its responses to paragraphs 1 through 81 of the Complaint. Bayer AG denies the remaining allegations of paragraph 82.

83. Bayer AG denies the allegations in paragraph 83, including subparts (a) through (l).

84. Bayer AG denies the allegations in paragraph 84.

85. Bayer AG denies the allegations in paragraph 85.

86. Bayer AG denies the allegations in paragraph 86.

87. Bayer AG denies the allegations in paragraph 87.

88. Bayer AG denies the allegations in paragraph 88.

COUNT III

89. In response to the allegations in paragraph 89, Bayer AG incorporates by reference its responses to paragraphs 1 through 88 of the Complaint.

90. Bayer AG admits that, prior to August 8, 2001, Bayer AG manufactured and sold cerivastatin sodium. Bayer AG also admits that, prior to August 8, 2001, Bayer Corporation marketed, promoted, distributed and sold Baycol® in the United States. Bayer AG

further admits that, prior to August 8, 2001, SmithKline Beecham Corporation d/b/a GlaxoSmithKline participated in the promotion of Baycol® in the United States. Bayer AG denies that Bayer Corporation, GlaxoSmithKline, GlaxoSmithKline plc and SmithKline Beecham Corporation manufactured Baycol®. Because of the vagueness and ambiguity of the remaining allegations in the first sentence in paragraph 90, Bayer AG is without knowledge or information sufficient to form a belief as to the truth of such allegations. Bayer AG denies the remaining allegations in paragraph 90, including subparts (a) through (g).

91. Bayer AG denies the allegations in paragraph 91.

92. Bayer AG denies the allegations in paragraph 92.

93. Bayer AG denies the allegations in paragraph 93.

94. Paragraph 94 sets forth conclusions of law to which no response is required. To the extent that a response is required, Bayer AG admits that, prior to August 8, 2001, Bayer AG manufactured cerivastatin sodium, and that, prior to August 8, 2001, Bayer Corporation sold Baycol® in the United States. Bayer AG denies that it violated any duty relating to Baycol® or the manufacture and/or sale of Baycol®, as alleged in the Complaint. Because of the vagueness and ambiguity of the remaining allegations in paragraph 94, Bayer AG is without knowledge or information sufficient to form a belief as to the truth of such allegations, including the allegation that Bayer AG had any duty to Plaintiff.

95. Because of the vagueness and ambiguity of the allegations of paragraph 95, Bayer AG is without knowledge or information sufficient to form a belief as to the truth of such allegations.

96. Paragraph 96 sets forth conclusions of law to which no response is required. To the extent that a response is required, Bayer AG denies that it violated any duty

relating to Baycol®, as alleged in the Complaint. Because of the vagueness and ambiguity of the remaining allegations in paragraph 96, Bayer AG is without knowledge or information sufficient to form a belief as to the truth of such allegations, including any allegation that Bayer AG had any duty to Plaintiff.

97. Bayer AG denies the allegations in paragraph 97, including subparts (a) through (d).

98. Bayer AG denies the allegations in paragraph 98.

COUNT IV

99. In response to the allegations in paragraph 99, Bayer AG incorporates by reference its responses to paragraphs 1 through 98 of the Complaint.

100. Bayer AG denies the allegations in paragraph 100.

101. Bayer AG denies the allegations in paragraph 101.

102. Bayer AG denies the allegations in paragraph 102.

103. Bayer AG denies the allegations in paragraph 103.

COUNT V

104. In response to the allegations in paragraph 104, Bayer AG incorporates by reference its responses to paragraphs 1 through 103 of the Complaint.

105. Paragraph 105 sets forth conclusions of law to which no response is required. To the extent that a response is required, Bayer AG admits that Baycol® was intended to be used to lower elevated plasma levels of total and low-density lipoprotein cholesterol and triglycerides, and to increase plasma levels of high-density lipoprotein cholesterol, in patients, and that, prior to August 8, 2001, Bayer Corporation marketed, sold, distributed and promoted Baycol® in the United States as safe for such use, according to prescribing information and

under the care of a physician or other health care provider. Bayer AG denies the remaining allegations of paragraph 105.

106. Bayer AG denies the allegations in paragraph 106.

107. Bayer AG denies the allegations in paragraph 107.

108. Bayer AG denies the allegations in paragraph 108.

109. Bayer AG denies the allegations in paragraph 109.

COUNT VI

110. In response to the allegations in paragraph 110, Bayer AG incorporates by reference its responses to paragraphs 1 through 109 of the Complaint.

111. Paragraph 111 sets forth conclusions of law to which no response is required. To the extent that a response is required, Bayer AG admits that, prior to August 8, 2001, Bayer Corporation marketed Baycol® in the United States as safe for use in accordance with prescribing information and under the care of a physician or other health care provider. Bayer AG denies the remaining allegations in paragraph 111.

112. Bayer AG denies the allegations in paragraph 112.

COUNT VII

113. In response to the allegations in paragraph 113, Bayer AG incorporates by reference its responses to paragraphs 1 through 112 of the Complaint.

114. Paragraph 114 sets forth conclusions of law to which no response is required. To the extent that a response is required, Bayer AG denies that it violated any law relating to Baycol®. Because of the vagueness and ambiguity of the remaining allegations in paragraph 114, Bayer AG is without knowledge or information sufficient to form a belief as to

the truth of such allegations, including any allegation that Bayer AG had any obligation to Plaintiff.

115. Paragraph 115 sets forth conclusions of law to which no response is required. To the extent that a response is required, Bayer AG denies the allegations in paragraph 115.

116. Bayer AG denies the allegations in paragraph 116.

117. Bayer AG denies the allegations in paragraph 117.

118. Bayer AG denies the allegations in paragraph 118.

COUNT VIII

119. In response to the allegations in paragraph 119, Bayer AG incorporates by reference its responses to paragraphs 1 through 118 of the Complaint.

120. Bayer AG denies the allegations in paragraph 120.

121. Bayer AG denies the allegations in paragraph 121.

122. Bayer AG denies the allegations in the Prayer for Relief. Bayer AG denies that Plaintiff is entitled to any relief whatsoever.

123. Bayer AG denies all allegations in the Complaint that relate or are directed to Bayer AG unless those allegations are expressly admitted in this Answer.

ADDITIONAL DEFENSES

1. Plaintiff's Complaint, and each and every count contained therein, fails to state a cause of action or claim upon which relief can be granted against Bayer AG.

2. Some or all of Plaintiff's claims are barred by the applicable statutes of limitations and/or statutes of repose.

3. Plaintiff's claims against Bayer AG are barred, in whole or in part, by laches, waiver and/or estoppel.

4. Plaintiff's claims are barred, in whole or in part, by Plaintiff's failure to mitigate alleged damages.

5. If Plaintiff sustained the injuries or incurred the expenses as alleged, which is expressly denied, said injuries or expenses were directly and proximately caused by the negligence or fault of parties other than Bayer AG, whether named or unnamed in Plaintiff's Complaint, over whom Bayer AG had no supervision or control and for whose actions and omissions Bayer AG has no legal responsibility. Plaintiff's recovery, if any, therefore should be apportioned in accordance with the applicable law.

6. The injuries and damages claimed by Plaintiff, if any, resulted from an intervening or superseding cause and/or causes, and any act or omission on the part of Bayer AG was not the proximate and/or competent producing cause of such alleged injuries and damages.

7. If Plaintiff suffered injuries as alleged in the Complaint, which is expressly denied, such injuries arose from, and were caused by, risks, hazards, and dangers knowingly assumed by Plaintiff. Plaintiff's recovery accordingly is barred or should be reduced by Plaintiff's assumption of the risk.

8. Baycol® is a prescription pharmaceutical which was available only upon the prescription of a licensed physician. The claims in the Complaint against Bayer AG accordingly are barred in whole or in part by the learned intermediary doctrine.

9. Plaintiff's recovery is barred and/or should be reduced under the applicable law because of Plaintiff's contributory negligence or fault and/or comparative negligence or fault.

10. Plaintiff's Complaint fails to state a claim upon which relief can be granted against Bayer AG in that the methods, standards, and techniques utilized with respect to the design, manufacture, marketing and sale of the prescription drug Baycol®, including adequate warnings and instructions with respect to the product's use included in the product's package insert and other literature, conformed to the applicable state of the art, and the product was designed, manufactured, marketed and sold in a reasonable and prudent manner based upon available medical and scientific knowledge.

11. Plaintiff's claims are barred as a matter of law pursuant to Restatement (Second) of Torts § 402A, comment k.

12. The prescription drug Baycol® complied with the applicable product safety regulations promulgated by the FDA. Compliance with such regulations demonstrates that due care was exercised with respect to the design, manufacture, testing, marketing and sale of this prescription drug, and that it was neither defective nor unreasonably dangerous.

13. Plaintiff's claims are preempted, in whole or in part, by federal law pursuant to the Supremacy Clause of the United States Constitution because of the federal regulation of prescription drug manufacturing, testing, marketing, and labeling.

14. If Plaintiff sustained the injuries or incurred the expenses as alleged, which is expressly denied, said injuries or expenses were caused by the unforeseeable alteration, improper handling, or other unforeseeable misuse of the prescription drug Baycol®.

15. Any claims by Plaintiff relating to alleged communications with regulatory agencies of the United States government are barred in whole or in part by operation of applicable law, including First Amendment rights to petition the government.

16. The alleged injuries and damages, if any, were the result of unavoidable circumstances that could not have been prevented by any person, including Bayer AG.

17. Plaintiff's Complaint fails to state a claim against Bayer AG upon which relief can be granted for several or joint and several liability.

18. Plaintiff's Complaint fails to join indispensable parties necessary for the just adjudication of this matter.

19. Plaintiff's Complaint fails to state a claim against Bayer AG upon which relief can be granted as to costs, attorneys' fees, pre-judgment interest and post-judgment interest.

20. Plaintiff's claims are barred in whole or in part because the commercial speech relating to Baycol® was not false or misleading and is protected under the First Amendment of the United States Constitution and the applicable state constitution.

21. Plaintiff's claims regarding warnings and labeling are barred in whole or in part by the doctrine of primary jurisdiction, in that the FDA is charged under law with determining the content of warnings and labeling for prescription drugs.

22. Plaintiff cannot state a claim with regard to warnings and labeling for prescription drugs because the remedy sought by Plaintiff is subject to the exclusive regulation of the FDA.

23. This court should abstain from adjudicating Plaintiff's claims relating to warnings and labeling in deference to the interpretation of regulations relating to prescription drug labeling by the FDA.

24. Upon information and belief, each item of economic loss alleged in the Complaint was, or with reasonable certainty will be, replaced or indemnified in whole or in part by collateral sources.

25. Plaintiff did not detrimentally rely on any labeling, warnings or information concerning Baycol®.

26. Plaintiff's alleged injuries and damages, if any, were the result of an idiosyncratic reaction which Bayer AG could not reasonably foresee.

27. Plaintiff's claims for breach of warranty are barred because Plaintiff failed to give timely notice of any alleged breach of warranty.

28. Bayer AG did not sell or distribute the prescription drug Baycol® directly to Plaintiff, and Plaintiff did not receive or rely upon any representations or warranties as alleged in the Complaint. Plaintiff's claims are barred by lack of privity between Plaintiff and Bayer AG.

29. Plaintiff's claims for breach of warranty, express or implied, are barred by the applicable provisions of the Uniform Commercial Code.

30. Plaintiff's Complaint fails to state a claim upon which relief can be granted under the Magnuson-Moss Act.

31. Plaintiff's purported allegations of fraud, deceit, misrepresentation and concealment do not comply with Rule 9(b) of the Federal Rules of Civil Procedure.

32. Plaintiff's Complaint fails to state a claim for fraud, deceit, misrepresentation and/or concealment.

33. Plaintiff's Complaint fails to state a claim against Bayer AG upon which relief can be granted for punitive or exemplary damages.

34. Plaintiff's claims for punitive or exemplary damages are barred under the applicable state and federal law. Permitting recovery of punitive or exemplary damages in this case would contravene Bayer AG's constitutional rights as reserved by the Fifth, Seventh, Eighth, and Fourteenth Amendments to the United States Constitution and other provisions of the United States Constitution and the applicable state constitution.

35. Because of the lack of clear standards, the imposition of punitive or exemplary damages against Bayer AG would be unconstitutionally vague and/or overbroad.

36. With respect to Plaintiff's demand for punitive or exemplary damages, Bayer AG specifically incorporates by reference any and all standards or limitations regarding the determination and enforceability of punitive or exemplary damages awards under the applicable state law.

37. No act or omission of Bayer AG was malicious, willful, wanton, outrageous, or done with actual malice or done with bad motive and/or with a reckless indifference to the interests of others, and Plaintiff's Complaint fails to state a claim upon which relief can be granted for punitive or exemplary damages. Plaintiff's Complaint seeks damages in excess of those permitted by law. Bayer AG asserts any statutory or judicial protection from punitive or exemplary damages that is available under the applicable law, and any award of punitive or exemplary damages is barred.

38. Plaintiff's claims asserted under the United States Food Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq., and other statutes and regulations, fail because those statutes and regulations do not contain or create any private cause of action.

39. Plaintiff's Complaint fails to state a claim upon which relief can be granted for negligence per se.

40. Under applicable state law, there exist no post-sale duties, including a post-sale duty to warn, in the present circumstances. Accordingly, Plaintiff's Complaint fails to state a claim against Bayer AG upon which relief can be granted for alleged breach of post-sale duties, including allegedly inadequate post-sale marketing or alleged post-sale duty to warn.

41. Plaintiff's claims may be barred in whole or in part by release.

42. Venue is improper.

43. This Court is not the proper forum and is not a convenient forum for the adjudication of Plaintiff's claims.

44. Bayer AG adopts and incorporates by reference all defenses pleaded by other defendants except to the extent that they are inconsistent with its defenses pleaded in this Answer.

45. Bayer AG reserves the right to amend its answer and separate and additional defenses to conform to such facts as may be revealed in discovery or otherwise.

WHEREFORE, Bayer AG prays that judgment be entered in its favor and against Plaintiff, and that it be awarded costs and such other and further relief as the Court deems just and appropriate.

JURY TRIAL DEMAND

Bayer AG demands a trial by jury on all issues so triable.

ECKERT SEAMANS CHERIN & MELLOTT, LLC

Dated: October 10, 2002

By_____

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CERTIFICATE OF SERVICE

I hereby certify that on this 10th day of October, 2002, the foregoing Answer and Defenses of Defendant Bayer AG was served by U.S. first class mail upon the following counsel of record:

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